Application Number 10/825,964
Amendment responsive to Office Action mailed August 8, 2007

REMARKS

This Amendment is responsive to the Final Office Action dated August 8, 2007, is submitted with a Request for Continued Examination, and constitutes a sufficient submission under 37 CFR § 1.114 for the Request for Continued Examination. Applicant has amended claims 19, 25, 39 and 53- 57, canceled claims 1-18, 46-52 and 63-71, and added claims 72 and 73. Claims 19–33, 35–45, 53–62, 72 and 73 are pending.

Claim Rejection Under 35 U.S.C. § 102

The Final Office Action rejected claims 19-26, 28, 29, 32, 33, 38-45, 53-58, 62 and 69-71 under 35 U.S.C. § 102(e) as being anticipated by Poezevera (US 6,890,306), and rejected claims 19-21, 23-31, 35-37, 59-61 and 69-71 under 35 U.S.C. § 102(e) as being anticipated by Ni et al. (US 2004/0111040, herein referred to as "Ni"). Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the amended claims. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

Independent Claims 19, 39 and 53

For example, both Poezevera and Ni fail to teach or suggest an implantable medical device or an implantable means that determines a value of a sleep metric that indicates a non-binary probability of the patient being asleep based on a plurality of monitored physiological parameters, as respectively required by Applicant's amended independent claims 19 and 39. Poezevera and Ni also fail to teach or suggest an implantable medical device that determines a non-binary probability of a patient being asleep based on a physiological parameter, where the physiological parameter is one of blood pressure, muscular activity, arterial blood flow or galvanic skin response, as recited by Applicant's independent claim 53, as amended.

In support of the rejection of claims 19, 39 and 53, as previously presented, the Office Action stated that Poezevera and Ni teach a binary indication of sleep state, and that a binary indication of sleep state provides probability information.[1] Although Applicant disagrees with

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[1] Office Action dated 8/8/07, page 5, item 6.

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this conclusion, Applicant has amended claims 19, 39 and 53 to recite a non-binary probability in order to advance prosecution.

Neither Poezevera nor Ni teach or even suggest the notion of using a sleep metric that indicates a non-binary probability of the patient being asleep as required by independent claims 19 and 39. Both Poezevera and Ni teach devices that make a binary determination of whether a patient is awake or asleep based on the comparison of a sensed physiological parameter, rather than a sleep metric that indicates a probability, to a threshold value.[2] In particular, Poezevera teaches a device that makes the binary determination based on individual comparison of two physiological parameters, minute ventilation and an acceleration sensor signal, to respective thresholds.[3] If the two parameters do not indicate the same state, i.e., sleep or awake, the trend of the minute ventilation signal is further analyzed to make the binary determination.[4] Similarly, Ni teaches a device that determines whether a patient is asleep by comparing a sleep detection signal from a sensor to a sleep threshold or index.[5] Ni explicitly states that, "so long as the first sleep-related signal exceeds the sleep threshold 560, the patient is determined to be awake," thus indicating the direct use of a physiological parameter, rather than a sleep metric that indicates a probability of the patient being asleep.[6] In contrast to the teachings of Poezevera and Ni, claim 19, for example, requires a determination of a value of a sleep quality metric that indicates a non-binary probability of the patient being asleep based on a physiological parameter.

Neither Poezevera, nor Ni, determines a non-binary probability of a patient being asleep, as recited by Applicant's independent claims 19, 39, and 53. Both references teach devices that determine whether the patient is either awake or asleep (i.e., a binary determination), rather than determining a non-binary probability of sleep. As described in Applicant's specification at paragraph [0020]:

> Use of sleep metrics that indicate a probability of the patient being asleep for each of a plurality of physiological parameters may further increase the reliability with which an implantable medical device may determine whether a patient is asleep. In particular, rather than a binary sleep or awake determination for each of a plurality of parameters, sleep metric values for each of a plurality of parameters

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[2] See, e.g., Poezevera, col. 4, ll. 56-64 and Ni, paragraph 53
[3] Poezevera, col. 4, ll. 56-64.
[4] Poezevera, col. 4, ll. 56-64.
[5] Ni, paragraph 57.
[6] Ni, paragraph 91.

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may be combined to yield an overall sleep metric value that may be compared to a threshold to determine whether the patient is asleep. In other words, failure of any one physiological parameter to accurately indicate whether a patient is sleeping may be less likely to prevent the implantable medical device from accurately indicating whether the patient is sleeping when considered in combination with other physiological parameters.

Nothing in the cited references mentions determining a non-binary probability of sleep, much less recognizes any benefits of determining a non-binary probability of sleep. Consequently, a skilled person would not have considered the features of independent claims 19, 39 or 53 obvious based on the teachings of the applied references.

Poezevera and Ni fail to teach each and every element of Applicant's claims 19, 39 and 53. Accordingly, Poezevera and Ni fail to anticipate independent claims 19, 39 and 53 and the rejection to claims 19, 39 and 53 should be withdrawn.

Dependent Claims

The claims dependent on independent claims 19, 39, and 53, namely claims 20–26, 28, 29, 32, 33, 38, 40–45, and 54–58, incorporate all of the limitations of the respective base claims, and therefore are patentable for at least the reasons expressed above. Moreover, the dependent claims recite a number of additional features that are likewise not present in the cited references. Applicant addresses some of the features below for purposes of illustration.

Poezevera and Ni fail to teach an implantable medical device that includes a processor that determines a value of an overall sleep metric based on the values of a plurality of sleep metrics, where each of the plurality of sleep metrics is based on a respective one of a plurality of physiological parameters, as recited by Applicant's claims 25 and 56 or a means for doing the same, as recited by Applicant's claim 42. Applicant's claims 26 and 27 recite a processor that determines a value of an overall sleep metric by averaging the values of the plurality of sleep metrics or by applying a weighting factor to at least one of the values of the plurality of sleep metrics, respectively.

As Applicant's disclosure recognizes, using an overall sleep metric value may help increase the reliability of the sleep determination, because failure of any one physiological parameter to accurately indicate whether a patient is sleeping may be less likely to prevent an

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accurate determination of whether a patient is asleep.[7] Poezevera and Ni do not contemplate determining an overall sleep metric value that is based on a plurality of physiological parameters. Instead, Poezevera and Ni rely on individual comparison of one or more physiological parameters to their respective threshold values to make a binary determination. Accordingly, the devices taught by Poezevera and Ni do not use an "overall sleep metric," and the cited references fail to anticipate Applicant's claims 25, 42, and 56.

As another example of the deficiencies of the cited references, the cited references fail to teach a processor that determines whether a patient is in one of a of a rapid eye movement (REM) sleep state or a nonrapid eye movement (NREM) sleep state, as recited by Applicant's dependent claim 30. The Office Action asserted that Ni teaches each and every element of claim 30. While Ni teaches a disordered breathing detection device that senses eye movement, Ni fails to teach a device that differentiates between different sleep states.[8] Accordingly, Ni does not teach a disordered breathing detection device that determines whether the patient is in one of a REM sleep state or a NREM sleep state.

Claims 33, 45, and 58 recite storage of information indicating when the patient is asleep for retrieval by a user. Poezevera and Ni make no mention of such a feature. The Office Action recognized that Ni does not anticipate claims 33, 45, and 58, but found that Poezevera anticipated claims 33, 45, and 58. In particular, the Office Action characterized the memory of the device taught by Poezevera as disclosing a processor that stores information for retrieval by a user (claims 33 and 58) or a means for storing information for retrieval by a user (claim 45). However, the memory in Poezevera is used for storing software instructions, rather than information indicating when the patient is asleep.[9] Poezevera makes no mention of even the desirability of storing information indicating when the patient is asleep for retrieval by a user, let alone include a description of such a feature.

Both Poezevera and Ni fail to disclose each and every limitation set forth in claims 19–33, 35–45, 53–62 and 69-71. For at least these reasons, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 19–33, 35–45, 53–62 and 69-71 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

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[7] Applicant's disclosure, paragraph [0020].
[8] Ni, paragraph [0052].
[9] Poezevera, col. 6, ll. 18–52.

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New Claims:

Applicant has added claims 72 and 73 to the pending application. No new matter has been added by the new claims. The new claims find support throughout the application as originally filed, including, for example, paragraphs [0011], [0038] and [0057].

The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the references fail to disclose or suggest a medical system comprising a plurality of sensors, each of the sensors generating a signal as a function of at least one physiological parameter of a patient, and an implantable medical device that includes a processor that monitors a plurality of physiological parameters of the patient based on the signals output by the sensors, for each of the plurality of physiological parameters, determines a respective one of a plurality of sleep metric values, each of the sleep metric values indicating a probability of the patient being asleep based on the respective physiological parameter, and mathematically combines the plurality of sleep metric values that each indicate that probability of the patient being asleep based on the respective one of the plurality physiological parameters to determine an overall sleep metric value that indicates an overall probability of the patient being asleep, as recited by claim 72.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.
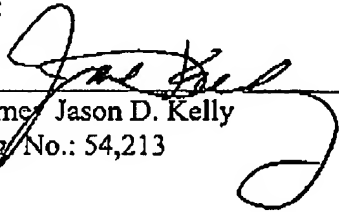
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     Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

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